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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/434,708	11/05/1999	HAMID BAND	B0801/7159(E	4277

7590 10/16/2003

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/434,708	Applicant(s) Band et al.
	Examiner G.R. Ewoldt, Ph.D.	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *10/15/02 and1/21/03* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-7, 9, 11, and 50* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7, 9, 11, and 50* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's Amendment and Remarks, filed 10/15/02, are acknowledged.

2. Applicant's new drawings, filed 1/21/03, have been found acceptable by the Examiner.

3. Claims 1-7, 9, 11, and 50 are pending and being acted upon.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7, 9, 11, and 50 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for,

an isolated nucleic acid molecule consisting of SEQ ID NO:1 or SEQ ID NO:3, or a nucleic acid molecule that differs from said nucleic acid molecules due to the degeneracy of the genetic code, or complements of said nucleic acid molecules, does not reasonably provide enablement for:

A) an isolated nucleic acid molecule which hybridizes to SEQ ID NO:1 under stringent conditions and which codes for a polypeptide that binds the Epidermal Growth Factor Receptor and downregulates its expression, or

B) an isolated nucleic acid molecule consisting of a unique fragment of SEQ ID NO:1 or a fragment of SEQ ID NO:3, or

C) an isolated nucleic acid molecule consisting of 2-200 contiguous nucleotides of SEQ ID NO:1, or

D) an isolated nucleic acid molecule which is a fragment of SEQ ID NO:1 which encodes a polypeptide which is immunogenic, or

E) a pharmaceutical composition comprising an isolated nucleic acid molecule consisting of SEQ ID NO:1 or an expression product thereof, for the reasons of record as set forth in Paper No. 18, mailed 4/08/02.

Applicant's arguments, filed 10/15/02, have been fully considered but they are not persuasive. Applicant argues that the addition of the new limitation requiring that the polypeptide encoded by SEQ ID NO:1 binds the Epidermal Growth Factor Receptor and downregulates its expression is sufficient to enable and

describe the claimed invention.

It remains the Examiner's position that the specification is insufficient to enable and describe the claimed nucleic acids intended for the treatment and diagnosis of essentially all known cancers (as set forth in the specification). It is noted that the claims have been limited to encompass only polynucleotides that encode polypeptides that bind the Epidermal Growth Factor Receptor and downregulates its expression, however, the specification still provides just a single example of a polynucleotide meeting the limitations of the claims. Note that the specification still discloses *no* fragments and *no* pharmaceutical compositions meeting the limitations of the claims. Also note that Applicant has not actually addressed the grounds for rejection, but rather has simply chosen to amend the claims and indicate that said amendment should be sufficient. Accordingly, for the reasons set forth previously, particularly Applicant's admission in the Background section of the specification that "Little is known at present about how cellular tyrosine kinases are regulated" (page 1), it remains the Examiner's position that the invention encompassed by the instant claims is neither adequately enabled nor adequately described.

6. Claims 1-7, 9, 11, and 50 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record as set forth in Paper No. 18, mailed 4/08/02.

Applicant has not addressed the rejection separately. See Examiner's response in paragraph 5 above.

7. No claim is allowed.

8. SEQ ID NOS:1 and 3 appear to be free of the prior art.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire

on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805 The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. **Please Note**: inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
October 14, 2003

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER